REMARKS

This Paper is submitted in response to the final Office Action mailed on September 30, 2005 having a shortened statutory response period ending on December 30, 2005. This Paper is timely filed within two months of the Office Action mail date, namely November 30, 2005. The Commissioner is hereby authorized to charge any additional fees to Deposit Account number 02-1818.

Claims 1-13 are pending in this application. Claims 14-21 have been canceled as a result of a Restriction Requirement. Applicants respectfully request that this paper be entered as it 1) places the claims in a condition for allowance and 2) requires only a cursory review by the Examiner.

Claims 1-7 and 11-13 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view of U.S. Patent No. 4,692,361 to Johnston et al. (*Johnston*) in view of U.S. Patent No. 6,326,010 to Sano et al. (*Sano*) . Claim 8 was rejected under 35 U.S. C. § 103(a) for allegedly being obvious in view of *Johnston* and *Sano* in further view of U.S. Patent No. 4,910,147 to Bacehowski et al. (*Bacehowski*). Claims 9-10 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Johnston* and *Sano* in further view of U.S. Patent No. 4,936,456 to Bell et al. (*Bell*). Applicants respectfully disagree with and traverse these alleged rejections for the reasons set forth below.

Johnston fails to disclose or suggest a flexible container that contains an albumin concentration of at least 20% as recited in the present claims. *Johnston* merely discloses a container that may be used to contain plasma. One of ordinary skill in the art would recognize that plasma has an albumin concentration of only about 3.4-5.4 g/dL. *See* Medline Plus article at page 2, set forth at Tab 1. At most, *Johnston* thereby suggests an albumin concentration only one fourth of the recited albumin concentration. As *Johnston* merely suggests an albumin concentration far below the recited albumin concentration of at least 20%, *Johnston* fails to disclose or suggest the subject matter of the present claims.

Sano fails to teach or suggest 1) a flexible film having 2) a fold area and 3) seals about the container periphery as recited in the present claims. Rather, *Sano* discloses a rigid, blow-molded container having a hermetically sealed top portion. *Sano*, col. 2 lines 41-49. One of ordinary skill in the art would readily recognize that *Sano's* rigid blow-molded container wholly lacks three claim elements—namely a flexible film, a fold area and peripheral seals. As the *Sano*

container wholly lacks a flexible film, a fold area, and peripheral seals, *Sano* does not teach or suggest a flexible container having a fold area and two peel seals as recited in the present claims.

It is an axiom of patent law that a reference as a whole must be considered for what it discloses. *In re Wright*, 6 USPQ2d 1959 (Fed. Cir. 1988). Consequently, when *Johnston* and *Sano* are properly read in their entireties, it is apparent that that no motivation exists to combine the disclosures of these references as such a combination would render *Sano* unsatisfactory for its intended purpose. *Sano* discloses a detailed blow-molding and container fill process for the provision of a rigid, blow-molded albumin-filled container that does not degrade the heat-sensitive albumin. *Johnston*, on the other hand, discloses a flexible heat-sealed polymeric bag that may contain plasma. Neither reference provides any motivation whatsoever to alter the structural features (*i.e.*, a rigid, seamless, non-folded, blow-molded, container) of the *Sano* container in order to form a flexible polymeric container. One of ordinary skill in the art would fail to find any motivation to alter the structure of the *Sano* container to have a fold area, a peripheral seam, and have flexibility merely because the *Sano* container holds albumin and the *Johnston* container holds plasma. Indeed, such a distorted reading of the references is not sound, particularly when such an interpretation would render the *Sano* container unsuitable for its intended purpose—namely, the provision of a rigid, blow-molded container. Consequently, when *Johnston* and *Sano* are properly read in their entireties, it is apparent that no motivation exists to combine the references as such combination would render the *Sano* container unsuitable for its intended purpose.

Bacehowski has no disclosure whatsoever directed to albumin, let alone an albumin concentrate of at least 20%. *Bacehowski* merely discloses a flexible container for storing cell cultures. *Bell* discloses a flexible bag made with peripheral peel seals and thereby teaches away from a container having permanent peripheral seals as recited in the present claims. *Bell*, col. 5 line 60 through col. 6 line 16, Figure 1.

Johnston has no disclosure whatsoever of a container containing an albumin concentration of at least 20%. *Sano* wholly lacks three recited elements— i) a flexible film, ii) a fold area, and iii) peripheral seals. No motivation exists to combine the *Johnston* and *Sano* references. *Bacehowski* wholly lacks any disclosure regarding albumin. *Bell* teaches away from a container having permanent peripheral seals. Applicants therefore respectfully submit that the subject matter set forth in the present claims is novel and nonobvious in view of the cited references.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly request an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____
Robert M. Barrett
Reg. No. 30,142
Cust. No. 29200

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Medical Encyclopedia

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Albumin - serum

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Blood test

Definition Return to top

This test measures the amount of albumin in serum, the clear fluid portion of blood.

How the test is performed Return to top

Blood is drawn from a vein (venipuncture) or capillary. The blood sample is placed in a centrifuge to separate the cells from the serum.

How to prepare for the test Return to top

The health care provider will advise you, if necessary, to discontinue drugs that may affect the test. Drugs that can increase albumin measurements include anabolic steroids, androgens, growth hormone, and insulin.

Why the test is performed Return to top

This test helps in determining if a patient has liver disease or kidney disease, or if not enough protein is being absorbed by the body.

Albumin is the protein of the highest concentration in plasma. Albumin transports many small molecules in the blood (for example, bilirubin, calcium, progesterone, and drugs). It is also of prime importance in maintaining the oncotic pressure of the blood (that is, keeping the fluid from leaking out into the tissues). This is because, unlike small molecules such as sodium and chloride, the concentration of albumin in the blood is much greater than it is in the extracellular fluid.

Because albumin is synthesized by the liver, decreased serum albumin may result from liver disease. It can also result from kidney disease, which allows albumin to escape into the urine. Decreased albumin may also be explained by malnutrition or a low protein diet.

Normal Values *Return to top*

The normal range is 3.4 to 5.4 g/dL.

Normal values may vary slightly from laboratory to laboratory.

What abnormal results mean *Return to top*

Lower-than-normal levels of albumin may indicate:

- ascites
- burns (extensive)
- glomerulonephritis
- liver disease (for example, hepatitis, cirrhosis, or hepatocellular necrosis "tissue death")
- malabsorption syndromes (for example, Crohn's disease, sprue, or Whipple's disease)
- malnutrition
- nephrotic syndrome

Additional conditions under which the test may be performed:

- diabetic nephropathy/sclerosis
- hepatic encephalopathy
- hepatorenal syndrome
- membranous nephropathy
- tropical sprue
- Wilson's disease

Special considerations *Return to top*

If you are receiving large amounts of intravenous fluids, the results of this test may be inaccurate.

Albumin will be decreased during pregnancy.

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Updated by: Christian Stone, M.D., Division of Gastroenterology, Washington University in St. Louis School of Medicine, St. Louis, MO. Review provided by VeriMed Healthcare Network.